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FEB 25 2003  
Attorney Docket No. CHIR-342/01US (PP00342.105)

PATENT

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By: Diane Kizer  
Diane Kizer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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TECH CENTER 1600 29

In re application of:

PIZZA et al.

Examiner: M. Borin

Serial No.: 09/528,682

Art Unit: 1631

Filed: March 20, 2000

Confirmation No.: 5794

For: IMMUNOGENIC DETOXIFIED MUTANT E. COLI LT-A TOXIN

Commissioner for Patents  
Washington, D.C. 20231

TRANSMITTAL OF RESPONSE

Enclosed are the following documents in response to the Election of Species Requirement mailed January 22, 2003 for the above-identified application:

- Amendment/Response
- Return receipt postcard
- No fee required

The Commissioner is hereby authorized to charge any appropriate fees under 37 C.F.R. §§1.16, 1.17, and 1.21 that may be required by this paper, and to credit any overpayment, to Deposit Account No. 03-3117.

Dated: 18 feb 03

Respectfully submitted,  
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Serial No. 09/528,682

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CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8

I hereby certify that these papers are being deposited with the U.S. Postal Service as first class mail with sufficient postage addressed to Commissioner for Patents, Washington, D.C. 20231, on 02/18, 2003, in Palo Alto, CA.

Diane Kizer

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

In Re Application of: ) Examiner: M. Borin  
PIZZA et al. )  
For: IMMUNOGENIC DETOXIFIED ) Group Art Unit: 1631  
MUTANT E. COLI LT-A TOXIN ) Confirmation No.: 5794  
Serial No.: 09/528,682 )  
Filed: March 20, 2000 )  
Atty. Docket No.: CHIR-342/01US (PP0342.105) )

FEB 28 2003

TECH CENTER 1600, 2003

**RESPONSE TO ELECTION OF  
SPECIES REQUIREMENT**

Commissioner for Patents  
Washington, D.C. 20231

Sir:

This paper is in response to the Election of Species Requirement mailed January 22, 2003 with a shortened statutory period of one month for response. Accordingly, this response is timely filed.

The Examiner, in the Election Requirement, required election of one species of "fragments of proteins of SEQ ID NO:1, 2, 3, 4) that require burdensome bibliographic, manual and computer searches." (Office Action, sentence bridging pages 2-3).

Applicants elect, with traverse, polynucleotides that encode amino acids numbered relative to SEQ ID NO:1.

As a threshold matter, Applicants traverse because the Examiner has not indicated what he considers the distinct species to be and on what basis they are distinct. Applicants note that sequences encompassed by the claims must include all three claimed characteristics, namely they must encode a fragment of at least 8 amino acids of SEQ ID NO:1-4; the fragment must include residue 72; and residue 72 must be substituted with an arginine. The Office has not delineated the differences between the allegedly distinct species encompassed by these claims and,

accordingly, Applicants cannot be required to elect a single species. In view of the lack of clarity, Applicants request that the election of species requirement be withdrawn.

Applicants also traverse on the grounds that it would not unduly burdensome to search all sequences together. Indeed, a search of the art for sequences having the recited claim limitations would necessarily reveal art relevant to all polynucleotides encompassed by the claims. For example, if the search for the smaller fragment reveals no relevant art, there will be no relevant art against larger fragments, which in **each and every** case must include the smaller fragments in order to fall within the scope of the claims. In view of the specific claim language, it is not required that each sequence be individually searched. Rather, for the reasons detailed above, at most, 8 overlapping sequences must be searched (e.g., sequences encoding fragments extending from 65-72; 66-73; 67-74; 68-75; 69-76; 70-77; 71-78; and 72-79). Thus, because searching a limited number of overlapping sequence is entirely routine and in **no** way burdensome, Applicants submit that the election of species requirement is improper and should be withdrawn.

Finally, it is to be understood that the election of species is for the purposes of preliminary search and examination only, and that upon allowance of a generic claim, applicants will be entitled to consideration of claims to the additional species.

Applicants expressly reserve their right under 35 USC §121 to file one or more divisional applications directed to any nonelected subject matter during the pendency of this application.

Respectfully submitted,

Date: 18 Feb 03

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